JAN 3 0 2002

510(k) Summary

Model 7500 Microcurrent TENS Device

Common/Classification Name: TENS Device, 21 CFR 882.5890

NewCare Products, LLC
182B Sandbank Road
Cheshire, CT. 06410

Contact: Doug Johnson, Prepared: September 12, 2001

A. LEGALLY MARKETED PREDICATE DEVICES

The Model 7500 Microcurrent TENS Device is substantially equivalent to the Healthonics MedRelief Microcurrent TENS device, which was cleared for marketing by FDA on February 21, 2001 under K003507. It is also substantially equivalent with respect to some characteristics to the Advance Medequip Model 850 Microcurrent TENS device, 510(k) number unknown, but the device is currently marketed, and to the Ito Trio (K990787).

B. DEVICE DESCRIPTION

A number of TENS and microcurrent devices have been cleared for marketing by FDA that have just a few discrete output settings, rather than having a continuously adjustable output. Such devices have been shrinking in size in recent years as advances in integrated circuits and other components allow for smaller circuits. Now NewCare Products is introducing a microcurrent TENS device that has the generator unit built-in to the back of the electrodes. By eliminating the bulky controls, the generator may be made very small and can be mounted on the electrode pad.

By providing three versions of the device, three different output levels are obtained. The three versions of the Model 7500 are equivalent to one traditional generator with three discrete output levels.

C. INTENDED USE

The **Model 7500 Microcurrent TENS Device** is intended to be used for the relief of chronic intractable pain.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The Model 7500 Microcurrent TENS Device is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices. The Model 7500 Microcurrent TENS Device has the same technological characteristics as the predicate devices. This premarket notification has described the characteristics of the Model 7500 Microcurrent TENS Device in sufficient detail to assure substantial equivalence.[1]

E. TECHNOLOGICAL CHARACTERISTICS

The Model 7500 Microcurrent TENS Device has the same technological characteristics as the currently marketed devices. All use discrete electronic components to generate electrical pulses that are delivered to the patient through a pair of patient electrodes. Two of the predicate devices employ software, but the Model 7500 and the Healthonics unit do not. The Model 7500 device is different from the predicate Healthonics device in that the three amplitude settings are realized through three separate versions of the device, each with different component values, while in the Healthonics Medrelief the three amplitude levels are realized through use of a single device with a three-position switch. However, this is not really a difference in technological characteristics since the underlying technology is the same.

F. TESTING

The Model 7500 has been tested and found to conform to the following standards:

- ANSI/AAMI NS4 (1985) Transcutaneous Electrical Nerve Stimulators
- Guidance for TENS 510(k) content (Draft: August 1994)
- UL2601-1, 2nd Edition (1997) Medical Electrical Equipment, Part 1: General Requirements for Safety, 2nd edition including amendments 1 and 2.
- CAN/CSA C22.2 No. 601-1-M90 Medical Electrical Equipment, Part 1: General Requirements for Safety including C22.2 No. 601.1S1-94 (IEC 601-1 Amendment 1:1991) Supplement No. 1-94 to CAN/CSA 22.2 No. 601.1-M90.

---

[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(l)(1) of the Federal Food, Drug, and Cosmetic Act.

- EN60601-1 (1990) Medical Electrical Equipment Part 1: General Requirements for Safety including amendments A1 + A2.
- IEC 60601-2-10 1st edition (1987) Particular Requirements for the Safety of Nerve and Muscle Stimulators.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

T. Whit Athey, Ph.D.
Senior Consultant
Representing NewCare Products, LLC
C. L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K013167
Trade/Device Name: Model 7500 Microcurrent TENS Device,
Versions MCT-F5, MCT-F50, and MCT-F500
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: January 3, 2002
Received: January 4, 2002

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

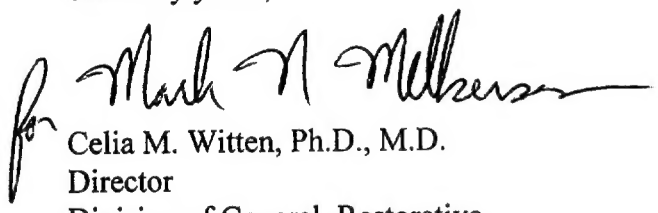
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate devices results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 10(k) Number (if known): K013167

Device Name: Newcare Products LLC MCT Micro Current Therapy

Indications For Use: The subject device is intended to be used for the symptomatic relief of chronic intractable pain.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) for Mark N Milhern (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013167/MNM